

Case No.: 16-1125

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

SIGMA-TAU HEALTHSCIENCE, INC., a.k.a. SIGMA-TAU
HEALTHSCIENCE, LLC

Petitioner-Appellant,

v.

UNITED STATES,

Defendant-Appellee.

APPEAL FROM THE UNITED STATES COURT OF INTERNATIONAL
TRADE, CASE NO. 1:11-CV-00093, JUDGE GREGORY W. CARMAN

**CORRECTED PRINCIPAL BRIEF OF PETITIONER-APPELLANT
SIGMA-TAU HEALTHSCIENCE, INC.**

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Dated: December 21, 2015

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Sigma-Tau HealthScience, Inc. a.k.a. Sigma-Tau HealthScience, LLC v. United States

Case No. 16-1125

CERTIFICATE OF INTEREST

Counsel for the Petitioner-Appellant Sigma-Tau HealthScience, Inc. certifies the following:

1. The full name of every party or amicus represented by me is:

Sigma-Tau HealthScience, Inc. a.k.a. Sigma-Tau HealthScience, LLC

2. The name of the real party in interest represented by me is:

Same as caption.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are listed below:

Sigma-Tau Industrie Farmaceutiche Riunite S.p.A. (parent of Sigma-Tau HealthScience, Inc.)

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or agency or are expected to appear in this court are:

Leslie Alan Glick, Porter Wright Morris & Arthur, LLP
John C. Monica, Jr., Porter Wright Morris & Arthur, LLP
Christopher C. Yook, Porter Wright Morris & Arthur, LLP

12/21/2015

Date

/s/ Leslie Alan Glick

Signature

Leslie Alan Glick

Printed Name

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STATEMENT OF RELATED CASES

In accordance with Rule 47.5 of the Rules of the United States Court of Appeals for the Federal Circuit, counsel for the Petitioner-Appellant makes the following statement:

- (1) To our knowledge no other appeal in, or from, the civil action brought before the United States Court of International Trade was previously before this, or any other appellate court under the same title or similar title.
- (2) A decision in this pending appeal may affect two cases on the United States Court of International Trade's suspension calendar: Court Nos. 1:11-cv-00274 and 1:11-cv-00364. These cases were stayed and placed on the United States Court of International Trade's suspension calendar by an order entered in 1:11-cv-00093 designating it as a test case (Dkt No. 26).

I. JURISDICTIONAL STATEMENT

Jurisdiction of the United States Court of International Trade for this action is found under 28 U.S.C. § 1581(a). This Court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(5). Petitioner-Appellant Sigma-Tau HealthScience, Inc. a.k.a. Sigma-Tau HealthScience, LLC (“Sigma-Tau”) timely filed a notice of appeal with the United States Court of International Trade on October 26, 2015. This appeal is from a final order of the United States Court of International Trade, dated September 3, 2015.

II. STATEMENT OF ISSUES

1. Whether the United States Court of International Trade (“CIT”) erred by not applying the relevant Chapter Note to HTSUS Chapter 29 which states: “Goods which could be included in two or more of the headings of this chapter are to be classified in that one of those heading which occurs last in numerical order” where the CIT found that the products at issue are classifiable under both heading 2923 Quaternary Ammonium Salts and heading 2936 Vitamins.

2. Whether the CIT erred by finding that Quaternary Ammonium Salts HTSUS 2923 is a more specific heading than Vitamins HTSUS 2936 under the rule of relative specificity where the only submission of record by the parties demonstrates that the term Quaternary Ammonium Salts encompasses numerous

products and that Vitamins is a more narrow and specific description of the products at issue.

III. STATEMENT OF THE CASE AND FACTS

This appeal centers around the CIT's failure to apply a binding HTSUS Chapter Note. Sigma-Tau prevails as a matter of law if the Chapter Note 3 to HTSUS Chapter 29 is applied.

The underlying dispute arose from the tariff product classification determination¹ of two L-Carnitine products imported by Sigma-Tau.² Although the dispute originated from U.S. Customs and Border Protection's ("Customs") August 27, 2010 ruling letter HQ H081683 classifying the products at issue under HTSUS subheading 3824.90.92 (JA at 4; Ruling Letter, JA at 1065-71), Customs conceded in its cross-motion for summary judgment that Customs' original classification was incorrect and argued instead for classification under HTSUS subheading 2923.90.00 (*see* JA at 10, 12-13; Def.'s Cross-Mot. for Summ. J., JA at 346). In its protests and motion for summary judgment, Sigma-Tau argued that the products are Vitamins and should be classified under HTSUS subheading

¹ Appellant Sigma-Tau appeals the CIT's Judgment and Opinion and Order dated September 3, 2015 (Dkt Nos. 74 and 75) (attached as JA at 1, 28).

² The two products referred hereinafter as "products at issue" are: (i) Acetyl L-Carnitine Taurinate Hydrochloride with 1.5% silica; and (ii) Glycine Propionyl L-Carnitine Hydrochloride, USP with 1.5% silica. *See* JA at 2.

2936.29.50. JA at 3-5. The parties did not dispute below that L-Carnitine is the primary and only biologically active component of the two products at issue. JA at 7. The CIT thus recognized that the issue before it was the proper classification of L-Carnitine. *See id.*

On the parties' cross-motions for summary judgment, the CIT found that the products at issue are *prima facie* classifiable as both Quaternary Ammonium Salts³ and Vitamins.⁴ However, the CIT failed to apply Chapter Note 3 to Chapter 29 in its initial analysis—a mandatory provision that would have resolved the question of which heading to apply and which Sigma-Tau had presented in its briefing (*see* Pltf.'s Reply at 14, JA at 973). Instead of applying the Chapter Note, the CIT looked to the rule of relative specificity under GRI 3(a). Applying that rule, the CIT incorrectly reasoned that the term “Quaternary Ammonium Salts” is more specific than “Vitamin Bt” because the former is enumerated in the title of heading while the latter is not. *See* JA at 20. The only authority before the CIT on this issue was an affidavit of Sigma-Tau's expert chemist, Dr. Yesu Das, that established the diverse variety of products chemically categorized as Quaternary

³ “The Court finds that since L-Carnitine is chemically known as a quaternary ammonium salt it is *prima facie* classifiable in HTSUS heading 2923.” JA at 15.

⁴ “Upon consideration of these scientific and lexicographic authorities, the Court finds that since L-Carnitine is commonly known as vitamin Bt it is *prima facie* classifiable in HTSUS heading 2936.” JA at 18.

Ammonium Salts, such as fabric softeners and pesticides, and providing explanation for why Vitamin is the more specific heading and description. Das Decl. ¶ 6-8, JA at 1073-74.

IV. SUMMARY OF ARGUMENT

As a matter of law, the CIT committed reversible error under GRI 1 because it did not apply Chapter Note 3 to HTSUS Chapter 29, which states that goods that can be included in two or more headings of Chapter 29 are to be classified by the one occurring last in numerical order. The CIT found that the products at issue fall into two possible headings within Chapter 29.⁵ It is undisputable that the Vitamins heading 2936 occurs last in numerical order after Quaternary Ammonium Salts heading 2923 and therefore prevails as the correct classification mandated by the Chapter Note. The CIT should be reversed on this ground alone.

Even if this omission were not dispositive, the CIT misapplied the rule of relative specificity under GRI 3(a). Instead of examining which provision has requirements that are more difficult to satisfy, the CIT stated: “the term ‘quaternary ammonium salts’ more specifically describes L-Carnitine than ‘vitamins’ because the chemical name wholly describes the products and is specifically enumerated as

⁵ “The parties submit that the products at issue fall under Chapter 29 ‘Organic Chemicals.’ The Court agrees.” JA at 14.

the first item in the headings.” JA at 20.⁶ This was not the correct legal analysis under the rule of relative specificity and ignored the only submission by the parties on the issue in the record which supports the opposite conclusion. Das Decl. ¶ 6-8, JA at 1073-74.

Under GRI 1 and Chapter Note 3 and alternatively under GRI 3(a)’s rule of relative specificity, the CIT should have found that Vitamins HTSUS 2936.29.50 prevailed, granted Sigma-Tau’s motion for summary judgment, and denied Customs’ cross-motion for summary judgment.

V. ARGUMENT

A. Standard of Review and General Rules of Interpretation

The CIT’s decision to grant summary judgment is reviewed *de novo* upon appeal and is reviewed for correctness as a matter of law. *See Totes, Inc. v. United States*, 69 F.3d 495, 498 (Fed. Cir. 1995). The first step of examining the proper meaning of heading terms is a question of law. *See Marcel Watch Co. v. United States*, 11 F.3d 1054, 1056 (Fed. Cir. 1993). The second step in the classification analysis of determining whether the products at issue fall within a heading is a

⁶ The CIT also included the following footnote: “This may have been a different case if ‘**vitamin Bt**’ itself was enumerated in heading 2936 but it is not.” JA at 20 (emphasis added).

question of fact and the CIT's findings may only be reversed for clear error. *See id.*

"The HTSUS scheme is organized by headings, each of which has one or more subheadings; the headings set forth general categories of merchandise, and the subheadings provide a more particularized segregation of the goods within each category." *Wilton Indus., Inc. v. United States*, 741 F.3d 1263, 1266 (Fed. Cir. 2013). "The classification of merchandise under the HTSUS is governed by the principles set forth in the GRIs [(General Rules of Interpretation)] and the Additional U.S. Rules of Interpretation." *Alcan Food Packaging (Shelbyville) v. United States*, 771 F.3d 1364, 1366 (Fed. Cir. 2014) (citing *Wilton Indus., Inc.*, 741 F.3d at 1266). The GRIs are applied in numerical order -- if a particular rule resolves the classification issue, the Court does not look to later GRIs. *See CamelBak Prods., LLC v. United States*, 649 F.3d 1361, 1364 (Fed. Cir. 2011). GRI 1 states that the classification is determined first by the heading and by any Section or Chapter Notes. *See Boen Hardwood Flooring, Inc. v. United States*, 357 F.3d 1262, 1264 (Fed. Cir. 2004). Therefore, GRI 3 should not be used if the classification can be established under GRI 1. *See Park B. Smith Ltd. v. United States*, 347 F.3d 922, 928-29 (Fed. Cir. 2003).

B. The CIT did not apply the relevant Chapter Note in its GRI 1 analysis which states that a good that can be classified in two or more Chapter 29 headings must be classified in the one “which occurs last in numerical order.”

In its GRI 1 analysis, the CIT erred by failing to apply the relevant Chapter Note 3 to determine which of two possible Chapter 29 headings applied. The CIT found that the products at issue are *prima facie* classifiable as both Vitamins heading 2936⁷ and Quaternary Ammonium Salts heading 2923⁸ -- both of which fall under Chapter 29 of the HTSUS.⁹ Sigma-Tau does not appeal the CIT’s finding that L-Carnitine is classifiable under either heading.

Customs’ main contention below, however, was that L-Carnitine is not a Vitamin because it is synthesized endogenously within normal, healthy adult humans. *See* JA at 17. Rejecting this argument regarding the “conditionally essential” nature of L-Carnitine, the CIT pointed to the example of Vitamin D because it is also produced endogenously yet is undisputedly a Vitamin under subheading 2936.29.50. *See id.* at 17-18. Sigma-Tau does not challenge the CIT’s conclusion that the products at issue fall under the Vitamins heading, which is a

⁷ JA at 18.

⁸ JA at 15.

⁹ *See* JA at 14 (CIT stating “The parties submit that the products at issue fall under Chapter 29 ‘Organic Chemicals.’ The Court agrees.”).

finding of fact subject to the “clearly erroneous” standard of review. Thus, the only issue before the Court is the CIT’s failure to apply Chapter Note 3.

According to GRI 1, a product’s “classification shall be determined according to the terms of the headings and any relevant section or chapter notes.”

Here, an applicable Chapter Note exists:

Goods which could be included in two more of the headings of this chapter are to be classified in that one of those headings which occurs last in numerical order.

Chapter Note 3 to HTSUS Chapter 29. As a matter of law, “[t]he terms of the headings and any relevant Section or Chapter Notes are paramount, i.e., they are the first consideration in determining classification.” Explanatory Note (V) to GRI 1; *see also Wilton*, 741 F.3d at 1266. This Court has recognized that “Chapter Notes are not optional interpretive rules, but are statutory law.” *Park B. Smith, Ltd.*, 347 F.3d at 926.

In addition to the clear directive of Chapter Note 3, an Explanatory Note provides further guidance. It states:

(E) Products potentially classifiable in two or more headings of Chapter 29 (Chapter Note 3)

Such products are to be classified in the heading placed last in numerical order amongst those which could be applied. For example, ascorbic acid could be regarded as a lactone (heading 29.32) or as a vitamin (heading 29.36); it should therefore be classified in heading 29.36.

World Customs Organization, *Harmonized Commodity Description and Coding System Explanatory Notes*, Explanatory Note 29(E) to Chapter 29 (attached as JA at 1079).¹⁰

In the case at hand, there is no dispute that the Quaternary Ammonium Salts heading 2923 and the Vitamins heading 2936 both lie within Chapter 29, and that the Vitamins heading occurs last in numerical order.¹¹ Thus, had Chapter Note 3 been applied by the CIT, the products at issue should have been classified under heading 2936.

Moreover, the example of ascorbic acid provided in Explanatory Note 29(E) is highly relevant and instructive to understanding the scenario presently before the Court. Like L-Carnitine, ascorbic acid can be classified by both its chemical structure, Lactone, and also as a Vitamin (it is one form of Vitamin C). Similar to

¹⁰ Explanatory Notes are not binding but they are “persuasive” and “generally indicative of the proper interpretation of the tariff provision.” *See Alcan Food Packaging*, 771 F.3d at 1367.

¹¹ Any potential arguments from Customs on appeal that the products at issue are not *prima facie* heading 2936 Vitamins as found by the CIT are inapposite. Chapter Note 3 does not require a finding that the products at issue are *prima facie* classifiable under two or more headings—it applies when goods “**could be** included in two or more of the headings of this chapter.” Chapter Note 3 to HTSUS Chapter 29 (emphasis added). The Explanatory Note also uses similar language, “Products **potentially classifiable** in two or more headings of Chapter 29.” Explanatory Note 29(E) to HTSUS Chapter 29. This is in contrast to the language of GRI 3(a), which includes the *prima facie* prerequisite.

Quaternary Ammonium Salts, there is a wide variety of products with disparate functions that have the chemical structure of Lactones, including fragrances, antioxidants, and antimicrobials. *See* Sigma-Aldrich, *Lactones*, Product Directory, <https://www.sigmaaldrich.com/chemistry/chemistry-products.html?TablePage=16270948> (attached as JA at 1075). Not only is ascorbic acid a Lactone, but it is also a Vitamin (Vitamin C). Therefore, although it is true that ascorbic acid can be described **chemically** as a Lactone, the Explanatory Note 29(E) and Chapter Note 3 establish that the **proper tariff classification** is as a Vitamin under heading 2936. The exact same analysis applies to L-Carnitine here—its chemical structure is a Quaternary Ammonium Salt, but it is also a Vitamin, which is the proper tariff classification under the same Chapter Note and Explanatory Note.

In another analogous case involving the application of Chapter Note 3, the CIT determined that a product called menadione was properly classified as a Vitamin where multiple Chapter 29 headings were at issue. *See Vanetta U.S.A., Inc. v. United States*, 306 F. Supp. 2d 1313, 1319 (Ct. Int'l Trade 2004) (“Here, defendant’s classification of plaintiff’s products under HTSUS chapter 29 (1994) is entitled to deference, **but not to the extent of foreclosure of their most correct classification under subheading 2936.90.00 in accordance with headnote 3 to that chapter.**”) (emphasis added). Similarly in the instant case, the CIT should

have held that the products at issue are Vitamins, not Quaternary Ammonium Salts under Chapter Note 3 to HTSUS Chapter 29.

C. The CIT should also be reversed because there is no support for its erroneous application of GRI 3(a)'s rule of relative specificity and because the only evidence of record requires the opposite conclusion.

Instead of applying Chapter Note 3 in its GRI 1 analysis, the CIT erroneously resorted to the rule of relative specificity under GRI 3(a) to determine whether heading 2923 or 2936 prevails. *See* JA at 18-20. As a threshold matter, the CIT should not have resorted to the GRI 3(a) rule of relative specificity because the proper classification should have been determined under GRI 1 by applying the relevant Chapter Note. *See Dependable Packaging Solutions v. United States*, 757 F.3d 1374, 1378 (Fed. Cir. 2014); *Mita Copystar Am. v. United States*, 160 F.3d 710, 712 (Fed. Cir. 1998). A similar situation arose in another case in which this Court rejected Customs' relative specificity analysis because a Chapter Note applied. This Court explained: "Rule 3(a) is applied after the prior rules, and does not override any section or chapter notes." *Park B. Smith Ltd.*, 347 F.3d at 928-29.

Setting aside the propriety of bypassing the Chapter Note, the CIT also misapplied the rule of relative specificity. GRI 3(a) states:

When, by application of rule 2(b) or for any other reason, goods are, *prima facie* classifiable under two or more headings, classification

shall be effected as follows: The heading which provides the most specific description shall be preferred to headings providing a more general description.

(emphasis added). When applying this rule of relative specificity and determining which heading provides the more specific description, “a court looks to the provision with requirements that are more difficult to satisfy and that describe the article with the greatest degree of accuracy and certainty.” *Bauer Nike Hockey USA, Inc. v. United States*, 393 F.3d 1246, 1251 (Fed. Cir. 2004) (citing *Len-Ron Mfg. Co. v. United States*, 334 F.3d 1304, 1313 (Fed. Cir. 2003)).

As an example, in *Archer Daniels Midland*, the Court weighed the specificity of “chemical products and preparations of the chemical or allied industries” versus “residual products of the chemical or allied industries.” *See Archer Daniels Midland Co. v. United States*, 561 F.3d 1308, 1317 (Fed. Cir. 2009). The Court determined that “chemical products” is a broad term and that “‘residual products’ comprise a **smaller and more specifically defined subset** of chemical products.” *Id.* (emphasis added).

The CIT’s analysis in the instant case was contrary to established legal precedent. Most of the relative specificity analysis in the opinion below was devoted a discussion of the general principle that use provisions prevail over *eo nomine* provisions. JA at 18-20. The CIT determined that the principle did not apply since the applicable portions of the two headings were *eo nomine* in its view.

Id. at 19-20. Only a single paragraph of the opinion was spent on substantively applying the rule of relative specificity. *Id.* at 20. The court reasoned that "Quaternary Ammonium Salts" is enumerated as the first item in heading 2923¹² while "Vitamin Bt" is not enumerated in heading 2936.¹³ *See id.* In a footnote the CIT wrote, "This may have been a different case if 'vitamin Bt' itself was enumerated in heading 2936 but it is not." *Id.* at n.18. The CIT only looked at the headings in its analysis, not the record before it regarding the products at issue.

The only evidence presented to the CIT on this issue by either party was the declaration of Sigma-Tau's expert analytical chemist, Dr. Yesu Das, which states in relevant part:

7. The term *quaternary ammonium salt* simply refers to the presence of the above-explained structure but does not describe its functionality. There are numerous different products that share this type of chemical structure falling into the broad category of *quaternary ammonium salts*. Accordingly, there are many chemical compounds that can be described as *quaternary ammonium salts*, but such description does not define the ultimate product. There are wide-ranging variety of products

¹² HTSUS heading 2923 states: "Quaternary ammonium salts and hydroxides; lecithins and other phosphoaminolipids, whether or not chemically defined."

¹³ HTSUS heading 2936 states: "Provitamins and vitamins, natural or reproduced by synthesis (including natural concentrates), derivatives thereof used primarily as vitamins, and intermixtures of the foregoing, whether or not in any solvent."

with this type of chemical structure with diverse applications, including the following:

Industrial: these chemical compounds possess surface-active properties, self-assembly characteristics, and detergency. These unique properties result in a variety of uses and popularity in domestic and industrial applications in shampoos, detergents, fabric softeners, and corrosion inhibitors, to name a few.

Antibacterial: these chemical compounds possess antibacterial properties and are in popular application in disinfectants and preservatives.

Agricultural (Pesticides): these chemical compounds possess herbicidal properties and have wide application in agriculture. Some of these compounds have been approved by the Environmental Protection Agency for this purpose.

Biochemical (Vitamins): these chemical compounds possess biochemical properties and have application/effect as vitamins. For example, a chemical compound with a terminal hydroxy group in its molecule is a vitamin (*Vitamin B Complex*) for its role in fat metabolism. The products at issue fall into this category.

8. Vitamins belong to a specific and unique category of bioactive compounds, based on their vital role in human body. The individual compounds in this functional category do not represent any single chemical category. So, chemical categorization is irrelevant to the vitamins. Therefore, the products at issue are most specifically and accurately classified as vitamins for their functional use, specifically as Vitamin B_T, a well-recognized vitamin since its discovery, and has since been known for its vital role in the body's energy production.

Das Decl. at ¶¶ 7-8, JA at 1073-74 (emphasis added). Dr. Das’ un rebutted expert declaration¹⁴ establishes that there are numerous and independent products that share the common chemical structure of a Quaternary Ammonium Salt—it is a very broad description. *See id.* at ¶ 6 (“The term *quaternary ammonium salt* very broadly describes a chemical compound’s partial structure.”) On the other hand, the number of products recognized as Vitamins is limited and a product is only considered a Vitamin to the extent it performs a specific function—it is a much more narrow and specific description. *See id.* at ¶ 8.

As expressed in *Faus Group*, the correct relative specificity analysis involves weighing the “the range of items covered by each heading or the range of uses of products in each heading.” *Faus Group, Inc. v. United States*, 581 F.3d 1369, 1374 (Fed. Cir. 2009). In *Russ Berrie & Co. v. United States*, the Court held that the “imitation jewelry” heading covers a narrower set of products and is thus more specific than “festive articles.” 381 F.3d 1334, 1338 (Fed. Cir. 2004). The Court explained that “festive articles include such disparate items such as ‘placemats, table napkins, table runners, and woven rugs.’” *Id.* (citation omitted).

Applying these principles here, Vitamins is a more specific description of the products at issue than Quaternary Ammonium Salts and is more difficult to

¹⁴ Customs did not submit expert testimony or reports in support of its relative specificity argument before the CIT. *See* Def.’s Reply, JA at 1056.

satisfy. Quaternary Ammonium Salts include a wide range of products with different uses—indeed completely unrelated functions in some instances like shampoos and pesticides. *See* Das Decl. at ¶ 7, JA at 1073-74. Not only is there is a wide range of products classifiable as Quaternary Ammonium Salts, the products covered by the heading also are disparate and independent from each other, as was the case in *Russ Berrie*. In contrast the vitamins heading is much narrower, only including “bioactive compounds, based on their vital role in [the] human body.” *Id.* at ¶ 8. As in *Archer Daniels Midland*, Vitamins can be considered a smaller and more specifically defined subset of Quaternary Ammonium Salts. *See Archer Daniels Midland Co.*, 561 F.3d at 1317.

Although Sigma-Tau believes the failure of the CIT to apply Chapter Note 3 to HTSUS Chapter 29 is alone grounds for reversal, assuming *arguendo* that GRI 3(a) applies, the proper classification of the products at issue is still Vitamins, not Quaternary Ammonium Salts, because the former describes the products at issue with the greatest degree of accuracy and certainty.

VI. CONCLUSION AND RELIEF SOUGHT

For the reasons stated above, Sigma-Tau asks the Court to reverse the CIT and enter an order granting its motion for summary judgment, denying Customs’ cross-motion for summary judgment, and declaring the proper classification for the two products at issue to be Vitamins HTSUS 2936.29.50.

Respectfully submitted,

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UNITED STATES COURT OF INTERNATIONAL TRADE

SIGMA-TAU HEALTHSCIENCE, INC.,
A.K.A. SIGMA-TAU HEALTHSCIENCE,
LLC,

Plaintiff,

v.

UNITED STATES,

Defendant.

Before: Gregory W. Carman, Senior Judge

Court No. 11-00093

JUDGMENT

This case having been duly submitted for decision; and the Court, after due deliberation, having rendered a decision herein; now therefore, in conformity with said decision, it is hereby

ORDERED, ADJUDGED AND DECREED that Defendant's Cross-Motion for Summary Judgment is granted and Plaintiff's Motion for Summary Judgment is denied; and it is further

ORDERED that the products at issue are properly classified under subheading 2923.90.00, HTSUS; and it is further

ORDERED that Plaintiff's Motion to Strike is denied; and it is further

ORDERED that judgment be awarded to Defendant.

/s/ Gregory W. Carman
Gregory W. Carman, Senior Judge

Dated: September 3, 2015
New York, New York

Slip Op. 15-102

UNITED STATES COURT OF INTERNATIONAL TRADE

SIGMA-TAU HEALTHSCIENCE, INC.,
A.K.A. SIGMA-TAU HEALTHSCIENCE,
LLC,

Plaintiff,

v.

UNITED STATES,

Defendant.

Before: Gregory W. Carman, Senior Judge

Court No. 11-00093

OPINION AND ORDER

[Plaintiff's motion for summary judgment is denied; Defendant's cross-motion for summary judgment is granted; Plaintiff's motion to strike is denied as moot.]

Dated: September 3, 2015

Leslie A. Glick, John C. Monica, Jr., and Christopher C. Yook, Porter Wright Morris & Arthur LLP, of Washington, DC, for plaintiff.

Alexander Vanderweide, Trial Attorney, Civil Division, Commercial Litigation Branch, U.S. Department of Justice, of New York, NY, for defendant. With him on the brief were *Benjamin C. Mizer*, Principal Deputy Assistant Attorney General, and *Amy M. Rubin*, Assistant Director, International Trade Field Office. Of Counsel on the brief was *Yelena Slepak*, Office of the Assistant Chief Counsel, International Trade Litigation, U.S. Customs and Border Protection, of New York, NY.

Carman, Senior Judge: Before the Court are cross motions for summary judgment and Plaintiff's motion to strike certain expert testimony. *See* Pl.'s Mot. for Summ. J., ECF No. 64, and Mem. in Supp. of Pl. Sigma-Tau HealthScience, Inc.'s Mot. for Summ. J., ECF No. 64-1 ("Pl's MSJ"); Def.'s Cross-Mot. for Summ. J. and Def.'s Mem. in Supp. of Its Cross-Mot. for Summ. J., ECF No. 68 ("Def.'s MSJ"); and Pl. Sigma-Tau HealthScience, Inc.'s Reply in Supp.

of its Mot. for Summary J./Opp'n to Gov't's Cross-Mot. and Mot. to Strike ("Pl.'s Reply"), ECF No. 69. Plaintiff Sigma-Tau HealthScience, Inc., a.k.a, Sigma-Tau HealthScience, LLC ("Sigma-Tau" or "Plaintiff") moves that the two products at issue in this case—(1) Acetyl L-Carnitine Taurinate Hydrochloride with 1.5% Silica and (2) Glycine Propionyl L-Carnitine Hydrochloride USP with 1.5% Silica (hereinafter collectively "products at issue" or "L-Carnitine")—are vitamins and properly classifiable as "vitamins" under the Harmonized Tariff Schedule of the United States ("HTSUS") subheading 2936.29.50, which carries duty free treatment. Defendant U.S. Customs and Border Control ("Customs" or "Defendant") cross-moves that the products at issue are not vitamins and properly classifiable as "quaternary ammonium salts" under HTSUS subheading 2923.90.00. For the reasons stated below, the products at issue are properly classified under HTSUS subheading 2923.90.00, and accordingly, Defendant's motion for summary judgment is granted and Plaintiff's motion for summary judgment is denied. In addition, Plaintiff's motion to strike is denied.

BACKGROUND

This action originally involved fifteen entries of eight products imported by Plaintiff from its Italian parent company into JFK International Airport, New York, between 2008 and 2010. Def.'s MSJ at 1. The eight products are listed in Table A:¹

¹ For ease of reference, the Court assigns product identification numbers to each of the subject products as shown in Table A.

Product ID No.	Product Chemical Name
1	Acetyl L-Carnitine Hydrochloride
2	Acetyl L-Carnitine Arginate Dihydrochloride, USP with 1.5% Silica
3	L-Carnitine Fumarate with 1.5% Silica
4	Lysine L-Carnitine Fumarate Hydrochloride with 1.5% Silica
5	L-Carnitine Inner Salt (also known as L-Carnitine Base)
6	L-Carnitine Hydrochloride
7	Acetyl L-Carnitine Taurinate Hydrochloride with 1.5% Silica (trade name L-Tauro)
8	Gycine Propionyl L-Carnitine Hydrochloride, USP with 1.5% Silica (trade name GlycoCarn)

Compl. ¶13. Between 2009 and 2010, Customs liquidated and/or reliquidated Plaintiff's entries, classifying Products 1, 3, 5, and 6 under HTSUS subheading K2923.90.00,² which entered duty free, and Products 2, 4, 7, and 8 under HTSUS subheading 3824.90.92,³ which carries a 5% duty. Def.'s MSJ at 2. The K designation in this subheading indicates duty-free status in accordance with HTSUS General Note 13.⁴ *Id.* at 2 n.2. Plaintiff timely filed four protests against Defendant's decision to classify Products 2, 4, 7 and 8 under HTSUS subheading 3824.90.92. *Id.* at 3. In its protests, Sigma-Tau argued that all of its products, even those that Customs classified

² HTSUS subheading 2923.90.00 provides for "Quaternary ammonium salts and hydroxides; lecithins and other phosphoaminolipids, whether or not chemically defined: Other."

³ HTSUS subheading 3824.90.92 provides for "Prepared binders for foundry mold or cores; chemical products and preparations of the chemical or allied industries (including those consisting of mixtures of natural products), not elsewhere specified or included: Other: Other: Other: Other: Other: Other."

⁴ Without the K-designation the HTSUS subheading 2923.90.00 carries a 6.2% duty.

as duty-free under HTSUS subheading K2923.90.90, should be classified under subheading 2936.29.50. *Id.*

Plaintiff applied for further review of Protest Number 4701-09-100897 regarding Products 1, 2, 7 and 8, which resulted in Customs issuing ruling letter HQ H081683 on August 27, 2010. *Id.* In that ruling, Customs confirmed that Product 1 was a “nonaromatic quaternary ammonium salt compound provided for in the Pharmaceutical Appendix, and thus properly classifiable duty-free under HTSUS subheading K2923.90.00.” *Id.* However, Customs also confirmed that Products 2, 7 and 8 “were mixtures of nonaromatic compounds, and were thus properly classifiable under HTSUS subheading 3824.90.92.” *Id.* Customs denied two of Plaintiff’s protests in part and denied two in full “in accordance with HQ H081683.” *Id.*

Subsequently, in December 2011, Customs issued amended laboratory reports, which concluded: (i) Products 2, 7, and 8 are separate chemically defined organic compounds and thus are properly classifiable under HTSUS Chapter 29 as quaternary ammonium salts; and (ii) Product 2 was provided for in the Pharmaceutical Appendix. *Id.* at 3-4.

On February 10, 2014, the parties agreed that Products 1 through 6 are provided for in the Pharmaceutical Appendix and thus are properly classifiable as duty free under HTSUS subheading K2923.90.00.⁵ Partial Stipulated J. and Order, ECF No. 37 (“Partial Stipulated Judgment”). Consequently, the two products remaining in controversy in this case are Product 7, which is known by its trade name as L-Tauro, and Product 8, which is known by its trade name as GlycoCarn. Def.’s MSJ at 4. Defendant explains that these two products could not be part of

⁵ The tariff classification for six of eight of the products agreed upon by parties in the Stipulated Judgment is Customs’ proposed provision but with a K designation which grants duty free entry.

the K-designation stipulation because “neither taurinate nor glycine are provided for in the Pharmaceutical Appendix, [thus] these two products are not entitled to duty-free status with the K-designation.” *Id.* The Clerk of the Court severed entries 237-1325768-3 and 237-1329667-3 from this case, since those two entries entirely encompassed products no longer at issue, assigned them a new case number, and disposed of that case by joint stipulation. *See* Court No. 14-00042, Stipulated J., ECF No. 3.

On October 20, 2014, Plaintiff moved for Referral to Court-Annexed Mediation and Defendant opposed. *See* ECF Nos. 48, 49. The Court denied the Motion for Referral to Court-Annexed Mediation in Slip Opinion 14-133, ECF No. 52. On November 7, 2014, Plaintiff moved to compel certain discovery but subsequently withdrew its motion. *See* ECF Nos. 50, 62. In its motion for summary judgment, Plaintiff also requests as a part of its summary judgment remedy “costs, expenses, and attorney’s fees, as may be recoverable by law.” Pl.’s MSJ at 35. Defendant counters that such request “is premature and wholly inappropriate at this time.” Def.’s MSJ at 4 n.6. In any case, Plaintiff has not filed for costs in the form of a Bill of Costs pursuant to USCIT Rule 54(d)(1) or for fees in the form of an application pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412(d), and USCIT Rule 54.1.

Plaintiff moves the Court for summary judgment, arguing that L-Tauro and GlycoCarn are “properly classified as ‘vitamins’ under HTSUS heading 2936.29.50 and thus should be duty free.” Pl.’s MSJ at 1. Defendant cross moves for summary judgment, arguing that these two products “are completely described by the terms of HTSUS heading 2923, as quaternary ammonium salts,” and thus should be classified under HTSUS 2923.90.00. Def.’s MSJ at 4.

DISCUSSION

A. Jurisdiction and Standard of Review

The Court has “exclusive jurisdiction of any civil action commenced to contest the denial of a protest, in whole or in part, under section 515 of the Tariff Act of 1930” pursuant to 28 U.S.C. § 1581(a) (2012).⁶ Summary judgment is appropriate when the record shows that “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” USCIT R. 56(a). Parties agree there is no dispute about the facts and this case is ripe for summary judgment. Pl.’s MSJ at 25; Def.’s MSJ at 6.

Although Customs enjoys a statutory presumption of correctness in its classification decisions, this does not apply to pure issues of law in a summary judgment motion before the Court. *Universal Elec. Inc. v. United States*, 112 F.3d 488, 492 (Fed. Cir. 1997). The Court “does not defer to Customs’ decisions because it has been tasked by Congress to conduct a *de novo* review, and to determine the correct classification based on the record made before it.” *Id.* at 493; *see also* 28 U.S.C. § 2640(a)(1). Ultimately, the Court’s “duty is to find the *correct* result, by whatever procedure is best suited to the case at hand.” *Jarvis Clark Co. v. United States*, 733 F.2d 873, 878 (Fed. Cir. 1984) (emphasis in original).

Resolution of a disputed classification “entails a two-step process: (1) ascertaining the proper meaning of specific terms in the tariff provision; and (2) determining whether the merchandise at issue comes within the description of such terms as properly construed.” *Pillowtex Corp. v. United States*, 171 F.3d 1370, 1373 (Fed. Cir. 1999). When “the nature of the

⁶ All references to the United States Code hereinafter refer to the 2012 edition, unless otherwise specified.

merchandise is undisputed, . . . the classification issue collapses entirely into a question of law.”

Cummins Inc. v. United States, 454 F.3d 1361, 1363 (Fed. Cir. 2006) (internal citations omitted).

B. Proposed Classifications

The parties agree that the proper classification of the two products at issue hinges upon the primary and only active component of the products, L-Carnitine. *See* Pl.’s MSJ at 4 (“L-Carnitine is the biologically active component of the two products.”); Def.’s MSJ at 22 (referring to “carnitine as “the lone biologically active component” of L-Tauro and GlycoCarn). The products at issue are listed as “L-Carnitine Compounds” on the protests. *See* Summons, ECF No. 1. Customs rulings demonstrate that subject merchandise which includes the active agent L-Carnitine is typically classified as L-Carnitine. *See, e.g.*, N011436 (June 1, 2007) (classifying Levocarnitine, also known as L-Carnitine, which is a trimethylammonium salt derived from an amino acid); NY F80631 (January 11, 2000) (classifying L-beta-hydroxy trimethylammonium butyric acid, also known as L-Carnitine base). Accordingly, the Court’s duty is to determine the proper classification of L-Carnitine, which will apply to the two products at issue.

1. HTSUS Heading 2936

Plaintiff contends that the products at issue are properly classified as vitamins in HTSUS subheading 2936.29.50.⁷ Pl.’s MSJ at 4. “Vitamins belong to a specific and unique category of

⁷ HTSUS subheading 2936.29.50 covers:

Provitamins and vitamins, natural or reproduced by synthesis (including natural concentrates), derivatives thereof used primarily as vitamins, and intermixtures of the foregoing, whether or not in any solvent: Vitamins and their derivatives, unmixed: Other Vitamins and their derivatives: Other: Other.

bioactive compounds, based on their vital role in the human body.” Decl. of Yesu T. Das, Ph.D.

(“Das Decl.”) at ¶ 8, Pl.’s MSJ at Ex. J, ECF No. 64-4. Dr. Das, a chemist, explains:

There is no single overarching common chemical structure of vitamins—vitamins are represented in a variety of chemical structures and no two vitamins have the same chemical structure. Therefore, products are classified as vitamins due to their functional use, not due a particular chemical structure.

Das Decl. at ¶5.

Sigma-Tau imports both products in “25 kg drums from Italy where it is produced as a bulk powder,” and “sells the powder to intermediate manufacturers in the United States that further process it into (i) single vitamin tablets and/or pills and (ii) sports drinks or protein/food bars.” Pl.’s MSJ at 4-5 (internal citations omitted). Plaintiff emphasizes that L-Carnitine “is also commonly known as ‘Vitamin Bt’ and appears on the HTSUS Pharmaceutical Appendix and other scientific sources.” *Id.* at 5 (internal citations omitted). Drawing on similarities with vitamin D, Plaintiff offers the following definition of vitamin Bt:

Vitamin Bt is produced in insufficient amounts by the human body for normal nutrition and must be supplemented by external sources, both in infants and adults. The two products at issue are simple analogs of Vitamin Bt in that their other chemical components have no biological activity in the human body and do not change the essential nature of the products. A deficiency in Vitamin Bt in children can lead to illness or death. In this way, Vitamin Bt is an essential nutrient to all humans. Clinical studies have shown that humans require an exogenous source of Vitamin Bt products from outside the body to supplement the body’s limited internal endogenous production. The principal biological basis for the necessity of Vitamin Bt is its role in the body’s energy generations. Specifically, it is a transporter for the fatty acids in the cells’ mitochondria. Without it, the body is not able to properly generate energy.

Id. (internal citation omitted). In support of its contention, Plaintiff provided expert testimony about vitamin Bt from a chemist, definitions of carnitine and vitamin Bt⁸ in the Merriam Webster dictionary, and excerpts from scientific texts. *See* Pl.’s MSJ at Ex. G.

Plaintiff further asserts that its proposed heading is “a principle use provision” and thus is “governed by the Additional Rule of Interpretation (ARI) 1(a): ‘[A] tariff classification controlled by use (other than actual use) is to be determined in accordance with the use in the United States at, or immediately prior to, the date of importation, of goods of that class or kind to which the imported goods belong, and the controlling use is the principle use.’” Pl.’s MSJ at 26 (citing *Primal Lite, Inc. v. United States*, 182 F.3d 1362, 1363 (Fed. Cir. 1999)). Plaintiff insists that it has “put forward an abundance of affirmative evidence demonstrating that its products at issue meet all of the *Carborundum* factors⁹ because [the products at issue] have all of the physical characteristics of vitamins, are sold in stores that specialize in vitamins (*e.g.* The

⁸ L-carnitine refers to the levo-optical rotation of carnitine. *See* Def.’s MSJ at 8 n.8. Parties agree that there is no functional difference between L-carnitine and carnitine and use these terms interchangeably. So will the Court.

⁹ The *Carborundum* factors, which are used to determine which goods are commercially fungible with the imported goods, include:

use in the same manner as merchandise which defines the class; the general physical characteristics of the merchandise; the economic practicality of so using the import; the expectation of the ultimate purchasers; the channels of trade in which the merchandise moves; the environment of the sale, such as accompanying accessories and the manner in which the merchandise is advertised and displayed; and the recognition in the trade of this use.

Aromont USA, Inc. v. United States, 671 F.3d 1310, 1312-13 (Fed. Cir. 2012) (citing *United States v. Carborundum Co.*, 63 CCPA 98, 536 F.2d 373, 377 (1976)).

Vitamin Shoppe), are purchased by other companies as vitamins, are used by end-users as vitamins, are advertised as vitamins, are deemed vitamins by many scholarly articles provided to Customs as part of Plaintiff's protests, and are recognized as vitamins in the industry in which Sigma-Tau operates as vitamin manufacturer." *Id.* at 27. To support its proposition that L-Carnitine is a vitamin, Plaintiff cites the deposition of Dr. Ken Hassen, CEO of Sigma-Tau (Dep. of Dr. Ken Hassen ("Hassen Dep."), Pl.'s MSJ at Ex. E, ECF No. 64-3), and the declaration of Dr. Das, expert chemist for Sigma-Tau. *Id.* at 28. Plaintiff asserts that Defendant offered no rebuttal evidence regarding how the products at issue are actually used, and therefore, "the evidence shows that the products at issue are properly classified as vitamins, specifically under HTSUS 2936.29.50." *Id.* at 29.

Plaintiff further asserts that the products at issue are properly classified by using the rule of relative specificity of GRI 3(a). Plaintiff purports that its principle use provision trumps Defendant's *eo nomine* provision because the "general rule" is that the product is "generally more specifically provided for under the use provision." *Id.* at 32 (quoting *BASF Corp. v. United States*, 497 F.3d 1309, 1315 (Fed. Cir. 2007)).

2. HTSUS Heading 2923

Customs contends that the products at issue are properly classified as quaternary ammonium salts in HTSUS subheading 2923.90.00.¹⁰ Def.'s MSJ at 7. While admitting that the "identity of Vitamin Bt as carnitine was established in 1951," Customs asserts that "the

¹⁰ HTSUS subheading 2923.90.00 covers:

Quaternary ammonium salts and hydroxides; lecithins and other phosphoaminolipids, whether or not chemically defined: Other.

description of carnitine as Vitamin Bt has little use or applicability today, and has no bearing on whether the substance functions as a vitamin in humans or is classified as a vitamin for tariff purposes.” *Id.* at 26 (internal citations omitted). Customs explains that the “t” of vitamin Bt stands for “*Tenebrio*,” a group of several mealworms that demonstrated a dietary need for carnitine in the original study. *Id.* Customs argues, however, that calling carnitine “Vitamin Bt” is a misnomer because “neither carnitine nor Vitamin Bt is recognized as a vitamin in humans.” *Id.* at 27.

Customs further contends that Plaintiff’s products are not akin to vitamin D. *Id.* at 28. Customs expounds that even though L-Carnitine “has an essential role in metabolism, it is not a vitamin, because the body of a normal individual makes a sufficient amount for daily needs.” *Id.* at 25 (quoting Def.’s MSJ at Ex. S, B. Burge, “Carnitine in Energy Production,” Healthline (July 1999) at 9). Customs offers that L-Carnitine is a conditionally essential nutrient only for rare people who, for “genetic or medical reasons,” cannot produce sufficient amounts in their body. *Id.* at 25 (internal citations omitted). Customs posits that Plaintiff’s “reliance on vitamin D’s classification designation to support its preferred tariff subheading is misplaced, as is [Plaintiff’s] comparison of vitamin D” to the products at issue. *Id.* at 28. Defendant explains that, unlike vitamin Bt, “vitamin D is specifically provided for *eo nomine*¹¹” under HTSUS subheading 2936.29.5020, and is “listed as a vitamin in the Explanatory Note to heading 2936.” *Id.* at 28-29. Defendant posits that vitamin D differs from L-Carnitine in that vitamin D “is usually produced

¹¹ *Eo nomine* means an item is “identified by name.” *Len-Ron Mfg. Co., Inc. v. United States*, 334 F.3d 1304, 1308 (Fed. Cir. 2003).

in quantities low enough to necessitate dietary supplementation for health” versus L-Carnitine, which is “sufficiently synthesized and abundant in our bodies.” *Id.* at 30.

Accordingly, Customs claims that Plaintiff’s proposed provision, HTSUS heading 2936, “does not even partially describe the products” at issue and that its own proffered provision, HTSUS heading 2923, “is the only heading that encompasses the two products at issue.” *Id.* at 7. Defendant asserts that “no analysis beyond GRI 1 is needed because the imported merchandise is not *prima facie* classifiable in more than one HTSUS provision.” *Id.*

3. HTSUS Heading 3824

HTSUS heading 3824 was the basis for Customs’ denial of Plaintiff’s protests pursuant to HQ H081683. *See* Pl.’s MSJ at 2. Large swaths of Plaintiff’s briefs are devoted to detailing Customs’ erroneous classification of the products at issue as “chemical products and preparations of the chemical or allied industries (including those consisting of mixtures of natural products), not elsewhere specified or included” under HTSUS subheading 3824.90.92.¹² *See, e.g.*, Pl.’s MSJ at 5-18; Pl.’s Reply at 1-3. Customs originally classified the products at issue under this tariff provision in HQ H081683, and Plaintiff argues that Customs is bound to the classification stated in that ruling letter in this litigation. *See* Pl.’s MSJ at 32. While the Court agrees that Customs was bound by the tariff provision stated in its ruling letter for the purpose of classifying entries, the Court disagrees that Customs is bound to argue for the application of an admittedly

¹² The Court notes that Plaintiff refers to this provision throughout its papers as merely “foundry mold materials,” but Defendant asserts that it “never classified the products at issue as ‘foundry mold material.’” Def.’s MSJ at 17 n.19. Rather, Defendant explains that its Newark laboratory originally erroneously classified the products at issue under the basket segment of this provision as “mixtures of nonaromatic compounds excluded from classification in Chapter 29, HTSUS.” *Id.* at 15.

erroneous classification in this litigation.¹³ While arguably useful as background, the Court finds that arguments regarding HTSUS subheading 3824.90.92 for the products at issue are moot because Customs correctly conceded “that HQ H081683 incorrectly classified the two products at issue” under HTSUS heading 3824. Def.’s MSJ at 18. Consequently Customs “disavowed the accuracy of this tariff designation.” Def.’s Reply to Pl.’s Resp. to Def.’s Cross-Mot. for Summary J. (“Def.’s Reply”) at 2. Consequently, Plaintiff’s assertions regarding Customs’ concession as an invalid attempt to change its classification are without merit. *See* Pl.’s MSJ at 17.

In the case at hand, the Court’s duty is to determine *de novo* the correct classification of the products at issue. Any admittedly erroneous classifications by Customs in the past are not pertinent to proper classification by the Court moving forward. The Court gives little weight to Plaintiff’s arguments regarding HTSUS heading 3824. Defendant’s concession of error regarding ruling letter HQ H081683 benefitted Plaintiff and led to a partial settlement of this case. The Court agrees with the parties that HTSUS heading 3824 is inapplicable to the products at issue in this case.

C. GRI Analysis

Classification of merchandise is governed by the HTSUS General Rules of Interpretation (“GRIs”). *Avenues in Leather, Inc. v. United States*, 423 F.3d 1326, 1333 (Fed. Cir. 2005). The GRIs direct “the proper classification of all merchandise and are applied in numerical order.”

¹³ It does not escape the Court’s attention that Plaintiff proposes a tariff classification here that differs from the one asserted on its entry papers.

Carl Zeiss, Inc. v. United States, 195 F.3d 1375, 1379 (Fed. Cir. 1999). The Court may not consult any subsequent GRI unless the proper classification cannot be determined by reference to GRI 1. *See Mita Copystar Am. v. United States*, 160 F.3d 710, 712 (Fed. Cir. 1998). According to GRI 1, “classification shall be determined according to the terms of the headings and any relative section or chapter notes[.]” The possible headings are to be evaluated without reference to their subheadings, which cannot be used to expand the scope of their respective headings. *See Orlando Food Corp. v. United States*, 140 F.3d 1437, 1440 (Fed. Cir. 1998). “Only after determining that a product is classifiable under the heading should the court look to the subheadings to find the correct classification for the merchandise.” *Id.* Tariff terms are “construed according to their common and commercial meanings, which are presumed to be the same absent contrary legislative intent.” *Len-Ron*, 334 F.3d at 1309; *see also Medline Indus., Inc. v. United States*, 62 F.3d 1407, 1409 (Fed. Cir. 1995) (“Tariff terms are construed in accordance with their common or popular meaning.”)

1. GRI 1

a. HTSUS Heading 2923

The parties submit that the products at issue fall under Chapter 29 “Organic Chemicals.” The Court agrees. Next the Court considers the possible headings under Chapter 29. The Court contemplates the first possible HTSUS heading, 2923, simply because it comes first in the numerical order. The first step to resolve a disputed classification is to ascertain “the proper meaning of specific terms in the tariff provision.” *Pillowtex*, 171 F.3d at 1373. This heading lists *eo nomine* chemical compounds, and the first enumerated chemical compound is quaternary ammonium salts. The next step is to determine “whether the merchandise at issue comes within

the description of such terms.” *Id.* It is undisputed that L-Carnitine is a quaternary ammonium salt. Accordingly, L-Carnitine is classifiable in HTSUS heading 2923. Further, a review of Customs rulings shows that Customs has previously classified other L-Carnitine products under this heading. *See, e.g.*, N011436 (June 1, 2007) (classifying L-Carnitine from the Czech Republic as tariff number 2923.90.00 with a free duty rate under EN13); NY D80631 (January 11, 2000) (classifying L-Carnitine from Japan as tariff number 2923.90.00); NY E82956 (June 18, 1999) (classifying Acetyl-L-Carnitine from Italy as tariff number 2923.90.00 with a free duty rate under EN13).¹⁴

Further, Plaintiff does not dispute that its products at issue could be included in this heading. Instead, Plaintiff argues that this heading is less specific under the rule of relative specificity pursuant to GRI 3(a) than its own proposed heading. The Court finds that since L-Carnitine is chemically known as a quaternary ammonium salt it is *prima facie* classifiable in HTSUS heading 2923.

b. HTSUS Heading 2936

The Court contemplates the next possible HTSUS heading, 2936, which provides for vitamins. The first step is to ascertain the meaning of the terms in the heading. *See Pillowtex*, 171 F.3d at 1373. This heading covers all kinds of provitamins and vitamins and their derivatives used as such. In construing a tariff term, the court may rely on its own understanding of the term

¹⁴ Defendant elucidates that NY E82956 is “a ruling not at issue in this case,” but a proposed modification to it was “the genesis of the amended laboratory reports,” which led Customs to reevaluate HQ H081683. Def.’s Reply at 3-4. This ruling letter has not yet been revoked, despite Plaintiff’s allegation.

as well as upon lexicographic and scientific authorities and other reliable sources. *Kahrs Int'l, Inc. v. United States*, 713 F.3d 640, 644 (Fed. Cir. 2013) (internal quotations omitted). The Court notes that vitamin Bt is defined as carnitine in Webster's Dictionary. *See Webster's Third New International Dictionary* 2559 (1981).¹⁵ Also, under the definition for "carnitine" are the words "called also *vitamin Bt*." *Id.* at 340.¹⁶ Further, Defendant does "not dispute that carnitine was called Vitamin Bt" when first discovered. Def.'s MSJ at 26.

¹⁵ L-Carnitine is vitamin Bt. *See* Vitamins and Health Supplements Guide, available at <http://www.vitamins-supplements.org/carnitine.php> (last visited Aug. 31, 2015).

¹⁶ "L-carnitine" is explained as follows:

L-carnitine supplements are used to increase L-carnitine levels in people whose natural level of L-carnitine is too low because they have a genetic disorder, are taking certain drugs (valproic acid for seizures), or because they are undergoing a medical procedure (hemodialysis for kidney disease) that uses up the body's L-carnitine. It is also used as a replacement supplement in strict vegetarians, dieters, and low-weight or premature infants.

L-carnitine is used for conditions of the heart and blood vessels including heart-related chest pain, congestive heart failure (CHF), heart complications of a disease called diphtheria, heart attack, leg pain caused by circulation problems (intermittent claudication), and high cholesterol.

Some people use L-carnitine for muscle disorders associated with certain AIDS medications, difficulty fathering a child (male infertility), a brain development disorder called Rett syndrome, anorexia, chronic fatigue syndrome, diabetes, overactive thyroid, attention deficit-hyperactivity disorder (ADHD), leg ulcers, Lyme disease, and to improve athletic performance and endurance.

(footnote continued)

The next step is to determine if the products at issue fall within the meaning of the terms. *Pillowtex*, 171 F.3d at 1373. Defendant asserts that L-Carnitine is a “conditionally essential nutrient” “principally used as ingredients in workout supplements, not vitamins.” Def.’s MSJ at 24, 33. Defendant further asserts that L-Carnitine does not fit into the definition of vitamin provided in the Explanatory Notes (“EN”) to Section VI, Chapter 29, Sub-Chapter XI:

Vitamins are active agents, usually of complex chemical composition, which are obtained from outside sources and are essential for the proper functioning of human or other animal organisms. They cannot be synthesised [sic] by the human body and must therefore be obtained in final or nearly final form (provitamins) from outside sources. They are effective in relatively minute amounts and may be regarded as exogenous biocatalysts, their absence or deficiency giving rise to metabolic disturbances or “deficiency diseases.”

While the Court may refer to the ENs accompanying the tariff provisions, the ENs are not binding. Upon review of this EN in particular, the Court notes that portions of it contradict the tariff term that it should be explaining, and therefore, the Court disregards those portions of the explanation. The portions of the EN which read that vitamins “*cannot* be synthesised [sic] by the

The body can convert L-carnitine to other amino acids called acetyl-L-carnitine and propionyl-L-carnitine. But, no one knows whether the benefits of carnitines are interchangeable. Until more is known, don't substitute one form of carnitine for another.

WebMD, available at <http://www.webmd.com/vitamins-supplements/ingredientmono-1026-l-carnitine.aspx?activeingredientid=1026&activeingredientname=l-carnitine> (last visited Aug. 31, 2015). This popular source lists L-Carnitine under the category of “vitamins and supplements.” *Id.*

human body” and “may be regarded as exogenous biocatalysts” directly contradict the fact that an enumerated vitamin, Vitamin D, in the tariff subheading is synthesized in the body and produced endogenously. *See* Pl.’s MSJ at 15, Def.’s MSJ at 28-29. A non-binding explanatory note that directly conflicts with a tariff’s enumerated items is afforded very little weight.

Accordingly, L-Carnitine is classifiable in HTSUS heading 2936.

Upon consideration of these scientific and lexicographic authorities, the Court finds that since L-Carnitine is commonly known as vitamin Bt it is *prima facie* classifiable in HTSUS heading 2936.

2. GRI 3¹⁷

When goods are *prima facie* classifiable under two headings in the HTSUS, “[t]he heading which provides the most specific description shall be preferred to headings providing a more general description.” GRI 3(a); *see also Kahrs*, 713 F.3d at 647. This is called the rule of relative specificity. *See Len-Ron*, 334 F.3d at 1313. Under this rule, the Court looks to “the provision with requirements that are more difficult to satisfy and that describe the article with the greatest degree of accuracy and certainty.” *Id.* (internal citations omitted). Plaintiff avers that the rule of relative specificity directs that use provisions trump *eo nomine* provisions in the HTSUS. *See* Pl.’s MSJ at 32-34; Pl.’s Reply at 13-14. It is a “convenient rule of thumb” that a “product described by both a use provision and an *eo nomine* provision is generally more specifically provided for under the use provision” but only when “the competing provisions are in balance.” *Kahrs*, 713 F.3d at 647 (internal quotations and citations omitted).

¹⁷ GRI 2 is inapplicable because it relates to incomplete or unfinished articles or mixtures or combinations.

It is undisputed that HTSUS heading 2923 is an *eo nomine* provision, but disagreement arises as to HTSUS heading 2936. While Plaintiff asserts that HTSUS 2936 is a use provision, Defendant counters that it is a hybrid of an *eo nomine* provision and a use provision. Def.'s MSJ at 33. Upon application of the *Carborundum* factors, Plaintiff concludes that the products at issue are principally used as vitamins. Pl.'s MSJ at 27-29. Therefore, Plaintiff asserts that its products are vitamins under the principal use provision. However, Defendant takes issue with Plaintiff's assertion that HTSUS heading 2936 is wholly a use provision.

Defendant parses the heading and offers that the first segment of the heading, "provitamins and vitamins, natural or reproduced by synthesis (including natural concentrates)," is an *eo nomine* provision, but the second segment "derivatives thereof used primarily as vitamins" is a use provision. Def.'s MSJ at 33. The Court agrees. Thus, the Court must decide whether L-Carnitine falls under the *eo nomine* or use part of heading 2936.

Plaintiff maintains that L-Carnitine is vitamin Bt, which falls under the tariff term "vitamins" within the *eo nomine* part of the provision. Pursuant to *Jarvis Clark*, the Court considers if L-Carnitine also falls under the use part of the provision, "derivatives thereof used primarily as vitamins" of HTSUS heading 2936. The Court first notes that the term "thereof" relates back to the first phrase, "provitamins and vitamins." The term "thereof" cannot mean merely any substance. Accordingly, to fall under the rubric of the use part of heading 2936, L-Carnitine would have to be a derivative of a vitamin or a provitamin and be used as a vitamin.

The Court then looks to the common meaning of these terms in Webster's Dictionary. The definition of the term "derivative" is "made up of or marked by elements or qualities of something else." *Webster's, supra*, at 608. The definition of provitamin is "a precursor of a

vitamin that can be converted into a vitamin in the organism.” *Id.* at 1827. The example provided in the dictionary is that ergosterol is a provitamin of vitamin D2. *Id.* Applying these definitions to L-Carnitine, the Court finds that L-Carnitine is actually vitamin Bt, not a derivative of vitamin Bt, and does not fall under the use part of the provision. Therefore, L-Carnitine only falls under the *eo nomine* segment of HTSUS heading 2936. Accordingly, the Court must compare the two competing provisions through an *eo nomine* lens.

Applying the rule of relative specificity to the terms “quaternary ammonium salts” and “vitamins,” the Court finds that the term “quaternary ammonium salts” more specifically describes L-Carnitine than “vitamins” because the chemical name wholly describes the products and is specifically enumerated as the first item in the heading.¹⁸ Hence, L-Carnitine is properly classified under HTSUS heading 2923. Next the Court looks for the proper subheading within heading 2923. Upon review of the possible subheadings, the Court finds that the proper subheading is 2923.90.00, which is a basket provision for “Other.”

3. General Note 13

The Court finally considers whether the products at issue are listed in the Pharmaceutical Appendix, which is designated with a K and afforded duty free treatment pursuant to General Note 13 to the HTSUS, which provides:

[w]henver a rate of duty of “Free” followed by the symbol “K” in parentheses appears in the “Special” subcolumn for a heading or subheading, any product (by whatever name known) classification the such which is the product of a country eligible for tariff treatment under column 1 shall be entered free of duty, provided that such product is included in the pharmaceutical appendix to the tariff

¹⁸ This may have been a different case if “vitamin Bt” itself was enumerated in heading 2936 but it is not.

schedule. Products in the pharmaceutical appendix include the salts, esters and hydrates of the International Non-proprietary Name (INN) products enumerated in table 1 of the appendix that contain in their names any of the prefixes or suffices listed in table 2 of the appendix provided that any such salt, ester or hydrate is classifiable in the same 6 digit tariff provisions as the relevant product enumerated in table 1.

General Note 13 to the HTSUS. Thus to qualify for K designation, the products at issue must be listed in both Table 1 and Table 2. Table 1 lists the base compound and Table 2 lists prefixes and suffixes around the base compound. Customs concedes that L-Carnitine is listed in Table 1; however, Customs postulates that the products at issue do not qualify for K designation because the prefixes—taurinate of L-Tauro and glycine of GlycoCarn—are not listed in Table 2. Plaintiff argues in the alternative that these products, if classified under HTSUS head 2923, qualify for duty free treatment because L-Carnitine is listed in Table 1, but Plaintiff does not even mention Table 2. *See* Pl.'s MSJ at 11 n.4. The Court finds Defendant's reading of General Note 13 to be the correct interpretation, requiring that the products at issue are found in both Tables 1 and 2. Taurinate and glycine are not found on Table 2, and the requirements for K designation are not satisfied. Therefore, the Court finds that L-Tauro and Glycocarn do not qualify for K designation. Accordingly, the Court holds that the products at issue are properly classified under HTSUS subheading 2923.90.00.

CONCLUSION

For the reasons stated above, the Court agrees with Defendant that tariff subheading 2923.90.00, HTSUS, applies to the products at issue. Plaintiff's Motion for Summary Judgment is therefore denied, and Defendant's Cross Motion for Summary Judgment is granted. Finally,

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Plaintiff's motion to strike "and preclude any purported expert testimony or opinions not properly disclosed or supported by scientific authority pursuant to Rules 26 and 37" is denied as moot. Pl.'s Reply at 8-10.¹⁹ Judgment will enter accordingly.

/s/ Gregory W. Carman
Gregory W. Carman, Senior Judge

Dated: September 3, 2015
New York, New York

¹⁹ The Court did not rely on Dr. Matthew Birck's testimony as an expert in its analysis.

CERTIFICATE OF SERVICE

I, Leslie Alan Glick, hereby certify that on December 21, 2015, I caused service of a copy of the Corrected Principal Brief via the Court's ECF system to the following party:

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CERTIFICATE OF COMPLIANCE WITH RULE 32(A)(7)(B)

Appellant Sigma-Tau and its undersigned counsel certify that this corrected principal brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) and contains 4,295 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6), and pursuant to those requirements, this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14 point font.

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